K012961

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510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Sulzer Orthopedics Converge Acetabular System.

Manufacturer:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	September 27, 2001
Contact Person:	Mitchell A. Dhority Director, Regulatory & Clinical Affairs
Classification Name:	Hip Joint Metal/Polymer/Metal Semi-constrained Porous-coated Uncemented Prosthesis, 21CFR 888.3358
Common/Usual Name:	Acetabular Shell Components
Trade/Proprietary Name:	Sulzer Orthopedics Converge Acetabular System

PRODUCT DESCRIPTION

The Converge Acetabular System consists of the following shell components:

I. Hemispherical

The Converge Hemispherical Shell is a porous coated, Ti-6Al-4V (ASTM F136) shell. The outer surface of the shell has CSTi porous coating (commercially pure titanium) to provide for biological fixation. The shell is available in various sizes ranging from 39mm to 65mm (in 2mm increments).

The shell features 2 screwhole plugs that are sintered in place. The screwhole plugs can be removed intraoperatively before or after implantation if the surgeon opts to enhance fixation of the shell with bone screws. When left in place (no supplemental screws used), the screwhole plugs limit material ingress and egress (e.g., tissue, debris particles, cement, etc.).

II. Rim-Flare

The Converge Rim Flare Shell is a Ti-6Al-4V metallic acetabular shell coated with CSTi porous coating. It is designed with an offset outer radius in the rim region which permits the loads to be transmitted to the periphery of the outer surface. An initial press-fit of the component is achieved by the offset radius in this region. Additionally, the outer design of the shell incorporates three pegs which are press-fit into the cancellous bone of the reamed acetabulum to minimize the potential for tilting or rotation of the device. The shell is available in various sizes ranging from 39mm to 71mm (in 2mm increments).

III. Revision

The Converge Revision Shell is a Ti-6Al-4V metallic acetabular shell coated with CSTi porous coating. The Revision shell has up to nine screwholes which allow for screw placement into the ilium, ischium and pubis. Those screwholes that are not utilized may be plugged after implantation to limit passage of tissue, debris particles, cement, etc. The shell is available in various sizes ranging from 43mm to 81mm (in 2mm increments).

All three Converge shells feature a central dome hole which allows for interface with the impactor/alignment instrument as well as for visualization of the acetabulum to ensure complete seating of the device. The dome hole may be plugged using a threaded cover to restrict unwanted material migration through the hole.

All three of the Converge shell components will use existing Inter-Op instrumentation and will mate with currently marketed Inter-Op Acetabular Inserts (oxygenless packaged polyethylene, Durasul, or Metasul).

SPECIFIC DIAGNOSTIC INDICATIONS

Components of the Converge Acetabular System are intended for use in total hip arthroplasty for treatment of the following:

- patient conditions of noninflammatory degenerative joint disease (NIDJD); e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- revision of a previously failed arthroplasty where there is sufficient bone stock to support the implant.

SUBSTANTIAL EQUIVALENCE

Substantial equivalence is based on comparison to the Inter-Op Acetabular System. The fundamental scientific technologies previously incorporated into the Inter-Op Acetabular System have not changed in the Converge Acetabular System. The main difference is relative to changes being made to the manufacturing process which should provide additional assurance of cleanliness. These manufacturing process changes have also necessitated some minor changes in design for the Converge, all of which were assessed relative to the Inter-Op and found to be acceptable.

Based on conformance with the design control requirements as specified in 21 CFR 820.30 and similarities in design, materials, sterilization, intended use and indications for use, we believe that the Converge Acetabular System is substantially equivalent to the previously cleared Inter-Op Acetabular System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2001

Mr. Mitchell A. Dhority
Director, Regulatory & Clinical Affairs
Sulzer Orthopedics Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K012961
Trade/Device Name: Converge Acetabular System
Regulation Number: 21 CFR §888.3350 and §888.3358
Regulation Name: hip joint metal/polymer semi-constrained cemented prosthesis; hip joint metal/poly/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: JDI and LPH
Dated: August 31, 2001
Received: September 4, 2001

Dear Mr. Dhority:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K012961

Device Name: Converge Acetabular System

Indications for Use:

Components of the Converge Acetabular System are intended for use in total hip arthroplasty for treatment of the following:

- patient conditions of noninflammatory degenerative joint disease (NIDJD); e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
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- revision of a previously failed arthroplasty where there is sufficient bone stock to support the implant.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

K012961

510(k) Number

(Optional Format 1-2-96)